IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

KENNETH CHRISTISON, Individually and as Surviving Spouse of ANNALEE CHRISTISON, Deceased, and as Personal Representative of the Estate of ANNALEE CHRISTISON, Deceased, Plaintiff, v. BIOGEN IDEC INC. AND ELAN PHARMACEUTICALS, INC., Defendant.	**MEMORANDUM DECISION AND ORDER DENYING MOTION TO DISMISS AND STRIKE** Case No. 2:11-cv-01140-DN-DBP District Judge David Nuffer

Defendants Biogen Idec Inc. ("Biogen") and Elan Pharmaceuticals, Inc. ("Elan") have filed a Joint Motion to Dismiss and Strike Mr. Christison's First Amended Complaint ("Motion").[1] For the reasons set forth below, the Motion is DENIED.

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[1] Defendants' Joint Motion to Dismiss and Strike Plaintiff's First Amended Complaint, docket no. 100, filed January 21, 2014.

I. FACTUAL ALLEGATIONS

The Motion must be measured assuming the truth of Mr. Christison's well-pled allegations.[2] Mr. Christison makes the following factual allegations in his First Amended Complaint.[3]

In May 2004, Biogen and Elan submitted an application to the FDA for approval of Tysabri® for the treatment of multiple sclerosis ("MS").[4] Tysabri®, also known generically as "Natalizumab," and formerly known as "Antegren," is an immunosuppressant drug designed to prevent lymphocytes from migrating through the bloodstream into the brain where they can cause inflammation and associated destruction of the myelin sheath, a fatty tissue covering nerve cells that helps nerve fibers conduct electrical impulses.[5]

Since 1992, well before the application was submitted to the FDA, Tysabri® had been linked to Progressive Multifocal Leukoencephalopathy ("PML"), a typically fatal brain disease caused by the "JC Virus," a strain of papovavirus that is ordinarily latent in the human kidney but which replicates in the brains of individuals with impaired immune systems.[6]

In November 2004, the FDA approved Tysabri® for the treatment of MS.[7] Shortly after approval, Defendants Biogen and Elan began to market and distribute Tysabri® in the United States.[8] Biogen and Elan marketed the drug pursuant to the terms of a Development and Marketing Collaboration Agreement which, among other things, established a Joint Steering

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[2] *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937 (2009).

[3] First Amended Complaint and Demand for Jury Trial, docket no. 96, filed January 2, 2014.

[4] *Id.* ¶ 11.

[5] *Id.* ¶ 14.

[6] *Id.* ¶ 15.

[7] *Id.* ¶ 12.

[8] *Id.*

Committee and required Biogen and Elan to work together to develop detailed procedures regarding the format, timing, and content of safety information, including labeling information.[9]

In February 2005, the FDA withdrew its approval after it received three separate reports of patients diagnosed with PML.[10] Of the three reported cases of PML, two patients died.[11] In March 2005, the New York Times published an article in which Dr. Lawrence Steinman, a professor of neurology and head of immunology at the Stanford University School of Medicine and leading expert on Tysabri® who participated in its original development, stated that no one should have been surprised that patients being treated with Tysabri® would contract PML.[12] Dr. Steinman stated that the risk of serious infections like PML was "unfortunately logical" given that Tysabri® works by interfering with the immune system.[13] The article also reported that Dr. Steinman said Biogen executives asked him to tone down his criticisms of Tysabri® after he had expressed his apprehensions about the drug in speeches and in an article published in the journal *Science* in July 2004.[14]

In February 2006, Defendants reported to the FDA they had conducted a clinical trial which resulted in no additional cases of PML.[15] Consequently, in June 2006, the FDA authorized the reintroduction of Tysabri® into the market but restricted its use to monotherapy to treat MS.[16] To gain FDA approval for reintroducing Tysabri® on the market, Defendants developed the Tysabri® Outreach: Unified Commitment to Health ("TOUCH") program, which requires

[9] *Id.* ¶ 17.

[10] *Id.* ¶ 23.

[11] *Id.*

[12] *Id.* ¶ 25.

[13] *Id.*

[14] *Id.*

[15] *Id.* ¶ 23.

[16] *Id.* ¶¶ 23, 24.

every Tysabri® prescriber, infusion site, and MS patient receiving Tysabri® infusions in the United States to enroll in the risk management program in order to monitor patients for any signs of PML.[17]

In February 2007, John F. Foley, M.D., Mrs. Christison's physician, began to treat Mrs. Christison's MS with Tysabri®.[18] Mrs. Christison had been diagnosed with MS in 1991, and began receiving Tysabri® infusions on a monthly basis beginning in February 2007.[19]

In July 2008, Shane Cooke, Chief Financial Officer of Elan, stated that "neurologists and their MS patients in North America and Europe were increasingly confident that Tysabri® . . . was safe when used on its own."[20] Cooke also said "the further we go (without any new PML cases), the more comfortable that people become and the more that patients demand to be put on Tysabri®."[21] At the time Cooke made his statements in July 2008, Defendant Biogen had developed a marketing strategy to promote the efficacy of Tysabri® while downplaying the risks of developing PML.[22] This strategy involved ghostwriting articles, using opinion leaders, and paying consultants to push the efficacy of Tysabri® in an effort to compete with the other MS drugs on the market.[23] Prior to July 24, 2008, Defendants reported twelve suspected PML cases linked to Tysabri® in the FDA's Adverse Event Reporting System but did not report them to the general public.[24]

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[17] *Id.* ¶ 24.

[18] *Id.* ¶ 50.

[19] *Id.* ¶¶ 49-51.

[20] *Id.* ¶ 28.

[21] *Id.*

[22] *Id.* ¶ 28.

[23] *Id.*

[24] *Id.* ¶ 30.

The FDA indicated that it was important that Biogen and Elan share PML outcomes and disability information with patients and prescribers, but Biogen and Elan never shared such information.[25] Biogen and Elan sent a Dear Healthcare Professional Letter advising of two PML adverse event cases, but failed to state that the longer treatment duration increased the risk of PML despite the fact that one patient had received infusions for 14 months and the other received infusions for 17 months.[26] Instead, Defendants stated that clinical vigilance is the most important factor in these cases.[27] Biogen continued to allege that there was no clear relationship between duration of treatment and developing PML.[28]

In March 2009, the FDA notified Biogen that its promotion of Tysabri® was misleading because Biogen "fail[ed] to communicate any risk information associated with the use of this product."[29] Between October 2008 and July 2009, nine additional cases of PML were publicly reported after treatment with Tysabri® for longer treatment duration.[30] After July 24, 2009, Defendants stopped sharing information about new cases with the public on their websites and instead opted to report cases by word of mouth to medical professional and patient groups.[31]

In July 2009, after twenty-nine treatments of Tysabri®, Mrs. Christison began to develop facial drooping, increased weakness, and visual difficulties.[32] An MRI was performed on August 19, 2009, which revealed that she had developed PML.[33] After her diagnosis of PML, Mrs.

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[25] *Id.* ¶ 38.

[26] *Id.* ¶ 32.

[27] *Id.*

[28] *Id.*

[29] *Id.* ¶ 36.

[30] *Id.* ¶ 33.

[31] *Id.* ¶ 34.

[32] *Id.* ¶ 52.

[33] *Id.*

Christison discontinued all Tysabri® infusions.[34] She died seven days later on August 26, 2009.[35] Her death certificate lists PML as a cause of death.[36]

In September 2009, two more cases of PML were reported in patients taking Tysabri®.[37] Biogen refused to comment on or confirm the existence of those PML cases.[38] In November 2009, Defendants announced that they were updating the U.S. label for Tysabri® to reflect the increased risk of PML when the drug is taken over a longer period of time.[39]

In January 2010, the number of confirmed cases of patients who developed PML after treatment with Tysabri® had risen to thirty-one, and by January 21, 2010, eight had died.[40] In February 2010, the FDA released a safety announcement warning patients and medical professionals that the risk of PML increases with each Tysabri® infusion received.[41] In March 2010, the FDA notified Biogen that its promotion of Tysabri®—a webcast to potential TOUCH prescribers and physicians—contained "false or misleading" information and "minimized important risks associated with the use of Tysabri® and omits the drug's approved indication."[42] During the webcast it was stated that the "majority of Natalizumab-treated patients who developed PML have survived and exhibit varying levels of disability."[43] At this time, it was known that approximately twenty percent (20%) of MS patients diagnosed with PML died

[34] *Id.*

[35] *Id.* ¶ 54.

[36] *Id.*

[37] *Id.* ¶ 35.

[38] *Id.*

[39] *Id.* ¶ 37.

[40] *Id.* ¶ 40.

[41] *Id.* ¶ 41.

[42] *Id.* ¶ 42.

[43] *Id.* ¶ 43.

shortly after diagnosis, and approximately forty percent (40%) of such patients were rendered disabled.[44]

In July 2010, Defendants revised the U.S. label for Tysabri® to reflect the increased risk of developing PML with longer treatment duration.[45]

In April 2011, the FDA issued a drug safety communication stating that patients who took an immune system suppressing medication prior to taking Tysabri® have been shown to be at an increased risk for developing PML.[46] In August 2011, an article in Lancet Neurology entitled "Natalizumab treatment for multiple sclerosis updated recommendations for patient selection and monitoring" found that previous use of multiple sclerosis treatment increases the risk of PML three or four times.[47]

In January 2012, the FDA issued a drug safety communication stating that testing positive for anti-JC Virus antibodies was an identified risk factor for PML, and that patients who are found to be anti-JCV antibody positive and have one or more of the other known risk factors for PML should carefully determine the benefits and risks of treatment.[48]

Prior to taking Tysabri®, Mrs. Christison and Mrs. Christison's prescriber were never warned that longer treatment duration, use of prior immunosuppressant drugs, or a positive test for anti-JCV antibodies would increase the risk of developing PML.[49] Defendants knew or

[44] *Id.*

[45] *Id.* ¶ 39.

[46] *Id.* ¶ 45.

[47] *Id.* ¶ 47.

[48] *Id.* ¶ 48.

[49] *Id.* ¶ 49.

should have known for years prior to 2009 that the risk of developing PML increases with the existence of these factors.[50]

This concludes the summary of Mr. Christison's factual allegations. The procedural background of this case will next be considered, followed by a discussion of the Joint Motion to Dismiss.

II. PROCEDURAL BACKGROUND

This case was filed in 2011 in California state court by Mr. Christison, a Utah resident. Biogen then sought and obtained removal of the case to the United States District Court for the Northern District of California whereupon the case was transferred to this Court.

After the case was transferred to this Court, Biogen and Elan each filed motions to dismiss Mr. Christison's complaint.[51] Those motions were granted, dismissing all of Mr. Christison's claims with prejudice with the exception of Mr. Christison's fourth cause of action for "Negligence," which was dismissed without prejudice.[52] Mr. Christison was granted leave to amend his complaint to restate this cause of action, and was instructed that in doing so he must

> assert[] specific facts about the existence of information that made the labeling of Tysabri® inadequate at times material to [Mrs. Christison's] ingestion of the drug, together with specific facts alleging that a change in warnings would have had an impact on the prescribing physician's decision to prescribe Tysabri® to [Mrs. Christison].[53]

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[50] *Id.* ¶ 57.

[51] Docket nos. 17 and 21 (Biogen), docket nos. 15 and 30 (Elan).

[52] Memorandum Decision and Order Regarding Defendants' Motions to Dismiss ("Order"), docket no. 95, filed December 26, 2013. Plaintiff's sixth cause of action for "Wrongful Death" was also dismissed (as an independent cause of action), but Plaintiff was allowed to restate the alleged wrongful death as predicate to Plaintiff's re-pleaded claim for negligence. *Id.* at 7, ¶ 8. Plaintiff was not granted leave to amend to pray for "Punitive Damages" without the filing of a separate motion. *Id.* at 7, ¶ 10. Plaintiff made no such motion.

[53] *Id.* at 6, ¶ 6.

Mr. Christison filed an amended complaint shortly thereafter asserting claims for negligence,[54] negligent failure to warn,[55] and negligent misrepresentation.[56] Biogen and Elan filed the instant Motion seeking dismissal of these negligence claims as well as a request to strike the amended complaint.[57]

III. DEFENDANTS' MOTION TO STRIKE IS DENIED

As a preliminary matter, Defendants' Motion to Strike Mr. Christison's Amended Complaint is DENIED. Defendants provide no explanation in their briefing as to why they have made a motion to strike, let alone why the motion to strike should be granted. The prior Order[58] explicitly granted leave to Mr. Christison to file an amended complaint to restate the negligence cause of action. Therefore, to the extent Defendants make a motion to strike Mr. Christison's First Amended Complaint, the Motion is DENIED.

IV. MOTION TO DISMISS STANDARD

Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a complaint may be dismissed if it fails to state a claim upon which relief may be granted.[59] While it is true that a complaint must contain only a "short and plain statement of the claim showing that the pleader is entitled to relief,"[60] the U.S. Supreme Court has recently explained:

> To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' [*Twombly*]. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. [*Id.*]. The plausibility standard is not akin to a 'probability

[54] First Amended Complaint at ¶¶ 58-71.

[55] *Id.* at ¶¶ 72-82.

[56] *Id.* at ¶¶ 83-90.

[57] Docket no. 100.

[58] Docket no. 95.

[59] Fed. R. Civ. P. 12(b)(6).

[60] Fed. R. Civ. P. 8(a)(2).

> requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully. *Ibid.* Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of 'entitlement to relief.' [*Id.*]
>
> Two working principles underlie our decision in *Twombly*. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. . . . Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not "show[n]"—"that the pleader is entitled to relief."[61]

Therefore, all factual allegations stated in Mr. Christison's First Amended Complaint will be accepted as true. Any legal conclusions stated in Mr. Christison's First Amended Complaint will not be accepted as true. More than a possibility of misconduct must be pled, and Mr. Christison must show that he is entitled to relief based on a plausible claim that the Defendants are liable for the alleged misconduct.

V. DISCUSSION

Mr. Christison raises three causes of action in his First Amended Complaint: (1) negligence; (2) negligent failure to warn; and (3) negligent misrepresentation. Defendants seek to dismiss all three of these causes of action. Each will be addressed in turn.

A. Negligence

To plead negligence in a pharmaceutical drug case in Utah, a plaintiff must allege facts showing "(1) that the defendant owed the plaintiff a duty, (2) that the defendant breached that

[61] *Iqbal*, 556 U.S. at 678-79 (citations omitted) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

duty, (3) that the breach of duty was the proximate cause of the plaintiff's injury, and (4) that the plaintiff in fact suffered injuries or damages."[62]

i. Duty is Sufficiently Alleged

The learned intermediary doctrine has been adopted in Utah.[63] This means that "manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient."[64] The contours of this duty include making "timely and adequate warnings to the medical profession of any dangerous side effects produced by its drug of which it knows or has reason to know."[65] "*The physician*, after having received complete and appropriate warnings from the drug manufacturer, *acts as a learned intermediary between the drug manufacturer and the patient* when preparing the drug prescription."[66] This is because the physician is in the best position "to combine medical knowledge and training with an individualized understanding of the patient's needs[.]"[67] Thus, under Utah law, a drug manufacturer's duty is to give timely, adequate, complete, and appropriate warnings to the prescribing physician such that the physician can understand possible side effects and prepare a suitable prescription program for a patient.

The Utah Supreme Court has also stated that the manufacturer's duty is heightened due to its position as an expert in its particular field:

> [I]t is important to point out that the drug manufacturer is held to be an expert in its particular field and is under a "continuous duty . . . to keep abreast of scientific developments touching upon the manufacturer's product and to notify the medical

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[62] *Tingey v. Radionics*, No. 04-4216, 193 F. App'x 747, 759, 2006 WL 2258872 (10th Cir. Aug. 8, 2006) (unpublished) (quoting *Webb v. Univ. of Utah*, 2005 UT 80, ¶ 9, 125 P.3d 906).

[63] *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 2003 UT 43, 79 P.3d 922.

[64] *Id.* at ¶ 20 (citation omitted).

[65] *Id.* (citing *Barson v. E.R. Squibb & Sons*, 682 P.2d 832, 835 (Utah 1984)).

[66] *Schaerrer*, 2003 UT 43, ¶ 20 (emphasis in original).

[67] *Id.*

> profession of any additional side effect discovered from its use." The drug manufacturer is responsible therefore for not only "actual knowledge gained form research and adverse reaction reports," but also for constructive knowledge as measured by scientific literature and other available means of communication.[68]

Has Mr. Christison satisfactorily pled such a duty? Mr. Christison alleges that Defendants Biogen and Elan had several duties as the manufacturer and distributor of a pharmaceutical drug. For example, Mr. Christison argues that Biogen and Elan, as co-marketers and developers of Tysabri®, had a duty to exercise reasonable care in the "testing, research, development, packaging, distribution, promotion, marketing, advertising, instruction, and sale of their product."[69] Mr. Christison also argues that "[(a)] Defendants had a continuing duty to ensure that the product they provided was safe and used correctly through proper testing, research, adequate instruction, post-market surveillance, and appropriate modifications;" "[(b)] a duty to anticipate the environment in which the product would be used against the reasonably foreseeable risks attending the product's use in that setting, including misuse or alteration;" "[(c)] a continuing duty to give adequate warning of known or reasonably foreseeable dangers arising from the use of Tysabri®;" "[(d)] a duty to provide adequate warnings and instructions, which means they had to be comprehensible to the average user, calculated to convey the material risks to the mind of a reasonably prudent person, and of an intensity commensurate with the danger involved;" "[(e)] a continuing duty to assure the product they provided was properly labeled and true to the representations Defendants made about it;" and "[(g)] a continuing duty to assure those writing and carrying out Mrs. Christison's infusions fully understood the nature, characteristics, and proper use of Tysabri® . . . [;]" among other duties relating to the products, packaging, instructions, and promotional material released in association with Tysabri®. Mr. Christison also

[68] *Barson*, 682 P.2d at 835-36 (alteration in original) (citations omitted).

[69] First Amended Complaint at ¶ 59.

alleges that Defendants were experts in their field and had entered into an agreement to jointly develop and market Tysabri®. Defendants, however, argue that many of the duties alleged by Mr. Christison are inapplicable due to the learned intermediary doctrine.[70]

While Defendants are correct that some of the duties alleged by Mr. Christison are incorrectly stated or are repetitive, Mr. Christison has sufficiently alleged that Defendants owed a duty. Mr. Christison has alleged that, as manufacturers and distributors of a prescription drug, Defendants were in a position to develop and market the drug, and therefore had a duty to exercise reasonable care in the testing, research, development, packaging, distribution, promotion, marketing, advertising, instruction, and sale of their product. Mr. Christison has also alleged that Defendants had a continuing duty to ensure that the product they provided was safe and used correctly, including "a continuing duty to assure those writing and carrying out Mrs. Christison's infusions fully understood the nature, characteristics, and proper use of Tysabri®."[71] These statements allege a duty on the part of the drug manufacturer to give timely, adequate, complete, and appropriate warnings to the prescribing physician.

However, Mr. Christison also alleges that "[a]t all relevant times, Defendants owed a duty to warn healthcare providers *and patients* adequately that, in patients being treated with Tysabri®, the risk of developing PML increases with longer treatment duration. *This duty extended to Mrs. Christison* and her prescriber Dr. John Foley."[72] These allegations that Defendants had a duty to provide warnings directly to the patient, Mrs. Christison, are incorrect and therefore they are stricken. While it is true that under the learned intermediary doctrine a drug manufacturer may be liable directly to a patient if the manufacturer fails to adequately warn

[70] Defendants' Joint Memorandum of Points and Authorities in Support of Motion to Dismiss and Strike Plaintiff's First Amended Complaint at 11 ("Defendants' Memo"), docket no. 101, filed January 21, 2014.

[71] First Amended Complaint at ¶ 59(g).

[72] First Amended Complaint at ¶ 56 (emphasis added).

the prescribing physician,[73] the manufacturer has no duty to directly warn a patient. Thus, Mr. Christison's allegations that Defendants owed a duty to warn the "average user" or a "reasonably prudent person"[74] are also stricken to the extent they attempt to allege a duty to warn a patient. The "average user" or a "reasonably prudent person" will be read as referring to Mrs. Christison's medical providers.

Mr. Christison has sufficiently alleged that Defendants owed a duty. The next question is whether Mr. Christison has also sufficiently alleged breach of duty.

ii. Breach is Sufficiently Alleged

A duty may be breached "by acting or by failing to act."[75] "A manufacturer will be held directly liable to the patient for breach of the duty to make timely and adequate warnings to the medical profession of any dangerous side effects produced by its drug of which it knows or has reason to know."[76]

Mr. Christison argues Defendants breached their duty when they "creat[ed] a product with defective warnings/instructions including failing to warn of the risk of PML with longer treatment duration, the increased risk of PML with prior use of immunosuppressant [sic] and the increased risk of PML if a patient has JCV positive antibodies[.]"[77] Mr. Christison alleges that Defendants knew and should have known for years prior to 2009 that the risk of developing PML increases significantly the longer Tysabri® is taken, yet Defendants failed to timely and adequately warn consumers and healthcare providers about that increased risk.[78] Mr. Christison

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[73] *Schaerrer*, 2003 UT 43, ¶ 20.

[74] First Amended Complaint at ¶ 59(d).

[75] *Barson*, 682 P.2d at 835.

[76] *Schaerrer*, 2003 UT 43, ¶ 20 (citing *Barson*, 682 P.2d at 835).

[77] First Amended Complaint at ¶60.

[78] *Id.* at ¶ 37.

also alleges that Defendants knew or should have known prior to 2009 that taking an immunosuppressant prior to Tysabri® could increase the risk of PML, yet failed to adequately warn about that increased risk as well.[79] Further, Mr. Christison alleges Defendants knew or should have known prior to 2009 that testing positive for the JC Virus increased the risk of PML, yet failed to adequately warn about that risk too.[80] Mr. Christison alleges facts that show multiple cases of PML when patients took Tysabri®, which, Mr. Christison suggests, should have indicated to Defendants that the risk factors noted above should have been included in the warning label.

Taken as true, these claims sufficiently allege breach. Defendants breached their duty if it is true that they knew or should have known prior to 2009 that the risk of developing PML increases significantly the longer Tysabri® is taken, or when taken after other immunosuppressant drugs, or after testing positive for anti-JCV antibodies, but failed to timely and adequately warn healthcare providers about this increased risk.

Although Mr. Christison also alleges that FDA warnings were not issued on these risks until after 2009, Mr. Christison alleges Defendants became aware of or should have known of these issues prior to 2009 because there was criticism in the medical community of Tysabri®, and before 2009 there were reported cases of patients contracting PML during their treatment with Tysabri®.[81] The time at which Defendants became aware of or should have known about these alleged risks is a question of fact that cannot be resolved on a motion to dismiss. Mr.

[79] *Id.* at ¶ 45.

[80] *Id.*

[81] *Id.* at ¶ 32.

Christison has pled "factual content that allows the court to draw the reasonable inference that the defendant" breached a duty to Mr. Christison.[82]

iii. Causation is Sufficiently Alleged

In order to plead sufficient facts regarding causation, Mr. Christison must allege that the breach of duty was the proximate cause of the injury.[83] Mr. Christison has alleged that Defendants' failure to timely and adequately warn Dr. Foley, Mrs. Christison's physician, was the proximate cause of his injury and that if Defendants had taken the proper steps to test, study, and warn doctors about the drug, the injuries and damages complained of would not have occurred. Indeed, it is plausible that if the warning label for Tysabri® had indicated the warnings Mr. Christison alleges it should have contained, Dr. Foley would have used his medical judgment to steer Mrs. Christison in a different direction. Therefore, Mr. Christison has pled sufficient facts regarding causation.

iv. Damages are Sufficiently Alleged

Mr. Christison alleges that as a direct and proximate result of Defendants' conduct, "Decedent's life was dramatically shortened, depriving Decedent of enjoyment of life, and robbing Decedent's family of Decedent's affection and service."[84] Further, "Decedent suffered pre-death physical and mental pain and suffering after Defendants' product caused Decedent's injuries and before Decedent died. Funeral, medical, and other necessary expenses were incurred as a result of Defendants' misconduct."[85] Taken as true, these claims allege a sufficient claim for damages.

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[82] *Iqbal*, 556 U.S. at 678.

[83] *Tingey*, 193 F. App'x at 759 (quoting *Webb*, 125 P.3d at 909).

[84] First Amended Complaint at ¶ 71.

[85] *Id.*

Therefore, taking Mr. Christison's well-pled allegations as true, he has alleged sufficient facts to state a plausible claim for negligence. Accordingly, Defendants' Motion to Dismiss Count I of the First Amended Complaint is DENIED.

B. Negligent Failure to Warn is Sufficiently Alleged

Mr. Christison's second cause of action is for "negligent failure to warn." This claim is similar to the first cause of action in that both claims rely on the allegation that Defendants failed to adequately warn that the risk of developing PML increases with longer treatment duration, with prior use of immunosuppressant drugs, and if the patient tests positive for anti-JCV antibodies. Both claims rely on the allegation that Defendants' failures caused Mr. Christison's injuries.

In Utah, a negligent failure to warn claim consists of the following elements: (1) defendant's failure to exercise reasonable care because he did not provide an adequate warning; (2) the lack of an adequate warning made the product defective and unreasonably dangerous; and (3) the lack of an adequate warning was a cause of plaintiff's injuries.[86] As with a negligence claim, the learned intermediary doctrine applies. Therefore, a drug manufacturer's duty is to provide an adequate warning to the prescribing physician, not to the patient.

Mr. Christison has sufficiently pled this cause of action. Mr. Christison claims that the risk of developing PML increases with longer treatment duration; that 42% of patients who had developed PML were taking an immunosuppressant prior to Tysabri®; and that 50-60% of the population has contracted the JCV strain, making it more likely that PML would be developed in those who took Tysabri®. Mr. Christison claims that the warning label did not mention any of these factors and that the drug was therefore "unreasonably dangerous when it left the possession

[86] Model Utah Jury Instructions CV1018 (2d ed. Aug. 15, 2014), http://www.utcourts.gov/resources/muji/; *See House v. Armour of America, Inc.*, 929 P.2d 340, 344 (Utah 1996).

of Defendants, in that it contained warnings insufficient to alert consumers and their physicians, including the Plaintiff and her physician [sic], to the dangerous risks and reactions associated with the drug, namely PML."[87] These failures, it is alleged, caused injury to Mr. and Mrs. Christison.

As discussed in the section addressing Mr. Christison's negligence claim, Mr. Christison's allegations that Defendants had a duty to provide warnings directly to the patient are incorrect. While it is true that a drug manufacturer may be liable directly to a patient if the manufacturer fails to adequately warn the prescribing physician,[88] under the learned intermediary doctrine, the manufacturer does not have a duty to give direct warnings to a consumer. The duty runs from the manufacturer to the prescribing physician. Accordingly, those allegations are stricken. However, because Mr. Christison alleges that the "warnings [were] insufficient to alert . . . physicians, including [Mrs. Christison's physician] to the dangerous risks and reactions associated with the drug," and because Mr. Christison has made factual allegations supporting this claim which must be accepted as true, Mr. Christison has adequately alleged a claim for negligent failure to warn. Defendants' Motion to Dismiss Count II of the First Amended Complaint is DENIED.

C. Negligent Misrepresentation is Sufficiently Alleged

Finally, Mr. Christison argues that Defendants have engaged in negligent misrepresentation. "Utah long ago acknowledged the tort of negligent misrepresentation, which provides that a party injured by reasonable reliance upon a second party's careless or negligent misrepresentation of a material fact may recover damages resulting from that injury when the second party had a pecuniary interest in the transaction, was in a superior position to know the

[87] First Amended Complaint at ¶ 79.

[88] *Schaerrer*, 2003 UT 43, ¶ 20.

material facts, and should have reasonably foreseen that the injured party was likely to rely upon the fact."[89] "Privity of contract is not a necessary prerequisite to liability."[90]

"Both negligent misrepresentation and general fraud claims must meet the heightened pleading requirements of Fed. R. Civ. P. 9(b)."[91] The determination of whether a negligent misrepresentation claim satisfies Rule 9(b) hinges on whether a plaintiff has included specific factual allegations to support his claim or, on the other hand, whether he has "fail[ed] to make any distinction among the various Defendants and only offers conclusory allegations that Defendants made fraudulent statements during the course of the parties' dealings."[92] For the claim to survive, "[t]he plaintiff must 'identify the offender' rather than simply describe misrepresentations in the passive voice."[93]

Here, Mr. Christison argues, citing his complaint, that the following facts support his claim for negligent misrepresentation:[94]

> Defendants requested that a physician involved in the research and development of Tysabri® tone down his apprehensions of the drug in speeches in 2004 and more specifically in the journal Science in July 2004. [First Amended Complaint] at ¶ 26.
>
> While Dr. Steinman was clearly criticizing Tysabri® and alleging that it was a dangerous drug, Shane Cook, the CFO of Elan stated in an interview with the Associated Press in July 24, 2008 that the "further we go (without any new PML cases), the more comfortable that people become and the more that patients demand to be put on Tysabri®." *Id*. at ¶ 27.

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[89] *Price-Orem Inv. Co. v. Rollins, Brown & Gunnell, Inc.*, 713 P.2d 55, 59 (Utah 1986).

[90] *Id.*

[91] *Heaton v. American Brokers Conduit*, No. 2:11-cv-531-TS, 2011 WL 3734201, *4 (D. Utah Aug. 24, 2011) (unpublished), *aff'd*, 496 F. App'x 873 (10th Cir. 2012) (unpublished) ("Finally, the district court recognized that Mr. Heaton fatally failed to plead his fraud and negligent misrepresentation claims with particularity as required by Fed. R. Civ. P. 9(b). . . . We perceive no error in the district court's analysis."); *see also Shah v. Intermountain Healthcare, Inc.*, 2013 UT App 261, ¶ 10, 314 P.3d 1079, 1084-85 (holding that Rule 9(b) applies to fraud claims, including negligent misrepresentation).

[92] Heaton v. American Brokers Conduit, 2011 WL 3734201, *5.

[93] Shah, 2013 UT App 261, ¶ 10.

[94] The following facts are quoted verbatim from Plaintiff's Opposition to Defendants Joint Motion to Dismiss and Strike Plaintiff's First Amended Complaint, docket no. 108, filed February 21, 2014.

During this timeframe, July 2008, two more cases of PML were announced and Defendants withheld information about those two PML cases from the public for at least two months prior to their announcement. *Id*. at ¶ 29.

Even more egregious is the fact that, prior to July 24, 2008, material information regarding an additional 12 PML cases had been withheld from the public and prescribers. These adverse events were quietly reported to the FDA's post-marketing safety surveillance program. *Id*. at ¶ 30.

When Defendants finally announced two confirmed cases of PML on August 1, 2008, the Defendants omitted information regarding the patients and Defendant Biogen spokeswoman Naomi Aoki stated "we don't want to get into the whole business of discussing suspected cases." *Id*. at ¶ 31.

During this timeframe in 2008, upon information and belief, Defendant Biogen and Elan Pharmaceuticals sent a Dear Healthcare Professional Letter advising of two PML adverse event cases, but failed to state that the longer treatment duration increased the risk of PML despite the fact that one patient had received infusions for 14 months and the other received infusions for 17 months. Instead, Defendants stated that clinical vigilance is the most important factor in these cases. Even worse, Biogen continued to allege that there was no clear relationship between duration [of] treatment and developing PML. *Id*. at ¶ 32.

Between October 29, 2008 and July 24, 2009, nine additional cases of PML were reported and Defendants ceased sharing information about new PML cases with the public. Biogen stated that any new cases would be reported by word of mouth. *Id*. at ¶ 34.

In September 2009, there were further omissions by Defendant Biogen. Two more cases of PML were reported in patients taking Tysabri®. One case was reported in the New England Journal of Medicine, and the other was reported by Ralf Gold of the Ruhr University Bochum in Germany, who presented the data at the European Committee for Treatment and Research in Multiple Sclerosis. Defendant Biogen refused to comment on or confirm the existence of those PML cases. *Id*. at ¶ 35.

Defendants' misrepresentations in 2009 were so egregious that the FDA notified Biogen's Senior Vice President of Regulatory Affairs that Biogen's promotion of Tysabri® [sic]. *Id*. at ¶ 36.

In yet another letter to Biogen on March 25, 2010, the FDA chastised Biogen for promotion of Tysabri® that contained "false or misleading" information. The letter explained that Defendant Biogen's promotional information regarding Tysabri® "minimized important risks associated with the use of Tysabri® and omits the drug's approved indication." The promotional material in question was a webcast to potential TOUCH prescribers and physicians. The primary concern with the webcast was the statement that the "majority of Natalizumab-treated patients who developed PML have

> survived and exhibit varying levels of disability." At the same time that Defendant Biogen was disseminating this information, it was known that PML was very often fatal with approximately twenty percent (20%) of MS patients deceased shortly after diagnosis and approximately forty percent (40%) of patients rendered severely disabled. Despite this fact, Biogen downplayed the disability and mortality rates of PML. *Id*. at ¶ 42-43.
>
> Defendants continued their pattern of omissions throughout 2010 and 2011. On April 22, 2011, the FDA issued a drug safety communication stating that patients who took an immune system suppressing medication prior to taking Tysabri® have been shown to be at an increased risk for developing PML. Defendants knew or should have known that taking an immunosuppressant prior to Tysabri® could increase the risk of PML given the literature stemming back from the 1990s and early 2000s relating to the JC Virus and PML. Additionally, Defendants knew that most patients would have taken immunosuppressant drugs prior to commencing Tysabri® given that it was a third or fourth line treatment. It is believed that approximately forty-two percent (42%) of patients with PML had been treated with an immunosuppressant prior to receiving Tysabri®. At no point, did Biogen or Elan warn Plaintiff that taking an immunosuppressant medication prior to a Tysabri® infusion could cause an increased risk for PML. *Id*. at ¶ 45-46.
>
> During this timeframe, Defendants failed to warn Ms. Christison, Ms. Christison's prescriber or the public that certain risk factors significantly increased the risk of PML. It was not until January 2012, 3 years after Ms. Christison's death that it was announced that patients who are found to be anti-JCV antibody positive and have one or more of the other known risk factors for PML should carefully determine the benefits and risks of treatment. The FDA warned that the estimated risk of PML with all three known risk factors increases to 11/1,000 users. *Id*. at ¶ 46, 48, 53.[95]

Thus, Mr. Christison alleges, Defendants, as manufacturers and distributors, had information about the dangerous side effects of Tysabri® before 2009, but misrepresented that information in the course of their business and for pecuniary gain;[96] Defendants acknowledged internally that there were safer alternatives that held the same efficacy as Tysabri®;[97] Defendants failed to exercise reasonable care in obtaining or furnishing information for others' guidance;[98] and Mrs. Christison's medical providers reasonably relied upon Defendants' expertise, skill,

[95] Plaintiff's Opposition to Defendants Joint Motion to Dismiss and Strike Plaintiff's First Amended Complaint at 17-19, docket no. 108, filed February 21, 2014.

[96] First Amended Complaint at ¶ 85.

[97] *Id.* at ¶ 86.

[98] *Id.*

judgment, and knowledge that Tysabri® was safe, which reliance was foreseeable.[99] Mr. Christison argues that these allegations adequately state with particularity a claim for negligent misrepresentation.[100]

Defendants do not address these specific allegations, which are accepted as true. Mr. Christison has stated a plausible claim for negligent misrepresentation under Rule 9(b). These allegations point to specific facts by identified actors at particular times. They also touch on the elements of the claim. Thus, a claim for negligent misrepresentation has been adequately stated under Rule 9(b). However, these allegations represent the entire basis for the negligent misrepresentation claim. The negligent misrepresentation claim cannot be expanded beyond these allegations. These allegations may be subject to later pre-trial challenges.

Defendants' Motion to Dismiss Count III of the First Amended Complaint is DENIED.

VI. CONCLUSION

Because Mr. Christison's First Amended Complaint contains legally sufficient factual allegations, Defendant's Motion to Dismiss is DENIED. This ruling holds that Plaintiff has pled enough factual allegations to survive the motion to dismiss, not that Defendants have actually engaged in negligence, negligent failure to warn, or negligent misrepresentation.

[99] *Id.* at ¶¶ 84, 87.

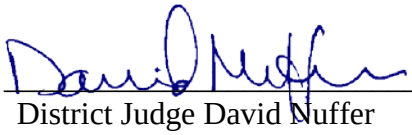
[100] Plaintiff's Opposition to Defendants Joint Motion to Dismiss and Strike Plaintiff's First Amended Complaint at 20, docket no. 108, filed February 21, 2014.

ORDER

IT IS HEREBY ORDERED that Defendants' Motion to Dismiss [101] is DENIED.

Signed December 18, 2014.

BY THE COURT



District Judge David Nuffer

[101] Defendants' Joint Motion to Dismiss and Strike Plaintiff's First Amended Complaint, docket no. 100, filed January 21, 2014.